510(k) #: k090439

SECTION 5. 510(K) SUMMARY

5. 510(K) SUMMARY

MAR 25 2009

510(k) SUMMARY
(per 21 CFR §807.92)

FORUM

GENERAL INFORMATION

Manufacturer:	Carl Zeiss Surgical GmbH Carl Zeiss Strasse 22 D-73446 Oberkochen, Germany 49 7364-20-2555 (phone) 49 7364-20-2035 (fax) Est. Reg. No. 2431026
Contact Person:	Kent W. Jones Vice President, RA/CA/QA/Compliance Carl Zeiss Meditec, Inc. 5160 Hacienda Drive Dublin, California 94568 925 557-4353 (phone) 925 557-4259 (fax)
Device	System, Image Management, Ophthalmic
Classification:	21 CFR 892.2050
Device Class:	II
Product Code:	NFJ
Common Name:	Picture Archiving and Communications System
Trade/Proprietary Name:	FORUM™

PREDICATE DEVICE

Company:	Nidek, Inc.
Device:	Nidek Advanced Vision Information System (NAVIS) (K013694)

SECTION 5. 510(K) SUMMARY

INDICATIONS FOR USE

FORUM is a software system application intended for use in storing, managing, and displaying patient data, diagnostic data, videos and images from computerized diagnostic instruments or video documentation systems through networks.

DEVICE DESCRIPTION

FORUM is a personal computer software system designed for storage, retrieval, and review of DICOM images, videos and reports originating from ophthalmic instruments and surgical microscopy. FORUM consists of two components: the FORUM Archive and the FORUM Viewer. The FORUM Archive, which contains both a server and client application, provides an archive for storage and administration of medical documents and patient data. The FORUM Viewer is an additional module to the client application which allows images, reports and videos stored in the archive to be reviewed. The FORUM Viewer also includes a modality worklist scheduling function.

When utilized together, the FORUM Archive and Viewer provide a complete workflow cycle from administering patient information via scheduling patients for examinations on connected instruments, through archiving the results of the examinations to retrieval and review of examination data.

SUBSTANTIAL EQUIVALENCE

It is the opinion of Carl Zeiss Surgical GmbH that FORUM is substantially equivalent to the Nidek Advanced Vision Information System (NAVIS). The indications for use statement for FORUM is similar to the indications for the predicate device cited in this application. A technological comparison demonstrates that FORUM is functionally equivalent to the predicate device.

Evaluation performed on FORUM supports the indications for use statement, demonstrates that the device is substantially equivalent to the predicate device and does not raise new questions regarding safety and effectiveness.

TECHNOLOGICAL CHARACTERISTICS

The fundamental technological characteristics of FORUM are similar to those of the predicate device. Both systems comprise a central database to store diagnostic documents (i.e. retinal images and reports of other ophthalmic diagnostic devices).

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These documents are imported from the diagnostic devices via a network connection.

Both systems are client – server systems which provide a software application (client) to view the data stored in the database (server). The viewer software allows the user to search for patients and their respective documents and to display multiple documents for comparison purposes. In both cases, the client software can be used to access the database from a remote location via web based access.

FORUM and the predicate device serve the same principal purpose of clinical usage and provide a wide range of comparable functionality for their users.

PERFORMANCE DATA

Performance testing was conducted on FORUM and was found to perform as intended. FORUM is DICOM compliant according to its DICOM conformance statement.

SUMMARY

As described in this 510(k) Summary, all testing deemed necessary was conducted on FORUM to ensure that the device is safe and effective for its intended use when used in accordance with its Instructions for Use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 25 2009

Carl Zeiss Meditec, Inc.
c/o Mr. Mark Job
Regulatory Technology Services LLC
1394 25th Street, NW
Buffalo, MN 55313

Re: K090439
Trade/Device Name: FORUM™
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: NFJ
Dated: March 12, 2009
Received: March 13, 2009

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4. INDICATIONS FOR USE STATEMENT

4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K090439

Device Name: FORUM™

Indications for Use:

FORUM is a software system application intended for use in storing, managing, and displaying patient data, diagnostic data, videos and images from computerized diagnostic instruments or video documentation systems through networks.

Prescription Use __x____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic and Ear, Nose and Throat Devices

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